NOV 22 2000

Premarket Notification
510(k) Summary of Safety and Effectiveness
The DRG Disposable Stethoscope Diaphragm with HealthShield™ Antimicrobial Compound

Company Information

Doctors Research Group, Inc.
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Wolcott, CT 06716
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Contact: Richard Deslauriers, MD

Registration Number: 1226001

Summary Preparation Date

August 24, 2000

Device Information

Trade name: DRG Disposable Stethoscope Diaphragm with HealthShield™ Antimicrobial Compound

Common name: Stethoscope Diaphragm

Classification name: Accessory to Manual Stethoscope and Electronic Stethoscope

Regulation Number: 870.1875

Product Code: LDE, DQD

Predicate Device

The following devices which incorporate silver and come in contact with skin have received 510(k) approval:

Product	Manufacturer	510(k) Number
Sterile Stockinette with Antimicrobial Agent	Deroyal Industries	K861196
Burlington Antimicrobial Stockinette	Balfour	K833122
3M Steri-Strip Antimicrobial Skin Closure	3M Company	K813265
Acticoat Silver Coated Dressing	Westain Technologies	K955453
Silver Foam Wound Dressing	Vitaphore	K914579
Pregelled Disposable Electrode, Silver-Silver	Labeltape Meditect	K865011

Device Description

The DRG Disposable Stethoscope Diaphragm with HealthShield™ Antimicrobial Compound is an accessory to DRG's manual and electronic stethoscopes, which are used to listen to body cavity sounds. The disposable diaphragm functions as both a diaphragm (allowing the stethoscope to detect sounds) and a chestpiece cover.

The diaphragm is composed of a thermoplastic elastomer and HealthShield™ Antimicrobial Compound. Healthshield™ is an agent contained in the plastic diaphragm that releases silver ions to the surface of the device. Silver is a well-known natural antimicrobial agent with broad spectrum antimicrobial and antifungal activity. In vitro testing demonstrated that the DRG Disposable Stethoscope Diaphragm with Healthshield™ Antimicrobial Compound shows 3-4 log kills (bacteriostatic) in direct inoculation tests of various bacteria on the surface of the diaphragm. This testing was conducted at 24 hours post inoculation.

Indications For Use

The DRG Disposable Stethoscope Diaphragm with HealthShield™ Antimicrobial Compound is intended for use to minimize surface contamination and facilitate cleaning and disinfection of the stethoscope.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 22 2000

Ms. Maureen Regan
Doctors Research Group, Inc.
143 Wolcott Road
Wolcott, CT 06716

Re: K002047
DRG Disposable Stethoscope Diaphragm with HealthShield™
Antimicrobial Compund
Regulatory Class: II (two)
Product Code: 74 DQD
Dated: August 25, 2000
Received: August 29, 2000

Dear Ms. Regan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Doctors Research Group, Inc.
143 Wolcott Road
Wolcott, CT 06716
(203) 879-9422

Statement of Indications For Use

510(k) Number (if Known): K002047

Device Name: DRG Disposable Stethoscope Diaphragm with HealthShield™ Antimicrobial Compound

Indications for use:

The DRG Disposable Stethoscope Diaphragm with HealthShield™ Antimicrobial Compound is intended for use to minimize surface contamination and facilitate cleaning and disinfection of the stethoscope.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

K002047

Prescription Use _ **OR** **Over-The-Counter Use**
(Per 21 CFR 801.109)